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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,775	04/28/2006	Tae-Yoon Kim	0070777-000021	9809

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EXAMINER	
MONSHIPOURI, MARYAM	
ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/577,775	KIM ET AL.	
	Examiner	Art Unit	
	Maryam Monshipouri	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-14 and 20-23* is/are pending in the application.

4a) Of the above claim(s) *9-14,22 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's response to restriction requirement filed 5/12/2008 is acknowledged. Applicant elected Group I, claims 1-8 without traverse. In response to applicant's request of rejoinder of claims 20-21 are hereby rejoined with elected invention.

Claims 9-14, 22-23 are withdrawn as drawn to non-elected invention. Claims 8 and 15-19 are canceled.

DETAILED ACTION

Claims 1-8 and 20-21 are under examination on the merits.

Priority

It is noted that this application is a National stage entry of PCT/KR04/02757. However, no priority data has been referred to in the disclosure. Applicant is advised to provide said priority data at the first page of the disclosure in response to this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase " substantially equivalent physiological activity" in claim 1 (and its dependent claims 3-5), claim 2(and its dependent claims 20-21) and claims 6-7 is unclear. Said phrase has not been specifically defined in the disclosure. In page 9, applicant refers to said phrase as including functional equivalents and derivatives of natural or recombinant intracellular superoxide dismutase (EC SOD)

protein. It is unknown what structures constitute functional or derivatives of said SOD and what are the metes and bounds of said phrase.

Claims 1-3, 5-7, 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1 (and its dependent claims 3 and 5), claim 2 (and its dependent claims 20-21) and claims 6-7 it is unknown which amino acid sequence applicant is referring to.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 20-21 are rejected under 35 U.S.C. 102(b) as anticipated by Marklund et al. “Marklund" (U.S. Patent No. 5,366,729, 11/1994, cited in the IDS) or, in the alternative, under 35 U.S.C. 103(a) as obvious over said patent.

Marklund teaches a pharmaceutical (see column 31), which comprises derivatives of EC SOD (from any source including mammalian). Said composition inherently prevents or treats skin diseases and by inherency works as cosmetic composition because it helps restore or rejuvenate skin appearance. However, Marklund does not specifically teach a pharmaceutical or cosmetic composition for skin disease treatment or a method of use thereof. Therefore, if said patent does not render the invention anticipated it at least renders it obvious, because Marklund claims (see

claim 14) methods of treatment of skin diseases utilizing said EC SOD compositions caused by perfusion or organ transplantation, implying that its SOD compositions may be utilized for treatment of skin disorders.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marklund et al. "Marklund" (US Patent No. 5,366,729, 11/1994, cited in the IDS). As stated above, Marklund teaches a generic pharmaceutical composition (see column 31) comprising EC SOD and derivatives thereof for treating skin disease as well as methods of prevention and treatment of dermatitis (see column 25) comprising administering EC-SOD and derivatives thereof encapsulated in liposomes to patients prior to this invention. Marklund does not specifically teach a pharmaceutical composition comprising EC SOD or derivative thereof for treating dermatitis

A the time the invention was made it would have been obvious to one of ordinary skill in the art to start with the method of Marklund and substitute the liposome composition administered with the generic pharmaceutical composition of Marklund in order to treat dermatitis.

One of ordinary skill in the art is motivated in replacing the liposomes of Marklund with the generic pharmaceutical composition comprising EC SOD or derivative thereof because such method would result in a faster acting treatment since the enzyme no longer is required to be released from the lipid bilayer and because liposome membrane would no longer accumulate in patient's liver resulting in toxicity and patient's discomfort rendering the invention obvious.

One of ordinary skill in the art has a reasonable expectation of replacing the liposomes in the method of Marklund with the generic pharmaceutical composition comprising EC SOD or derivative thereof because such methods are merely routine in the prior art.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marklund et al. "Marklund" (cited above) in view of Trova et al. (WO 96/40223, issued 12/1996). As stated above, Marklund teaches a pharmaceutical composition comprising EC SOD or derivative thereof for treating skin disease prior to this invention. Marklund does not teach an EC SOD consisting of SEQ ID NO:11 of this invention.

At the time the invention was made it would have been obvious to one of ordinary skill in the art to start with the composition of Markund and substitute its enzyme with that of Trova. One of ordinary skill in the art is motivated in substituting the enzyme of Marklund with the human EC SOD of Trova because the enzyme of Trova being from human source is expected to act more efficiently on humans, rendering the invention obvious.

Finally one of ordinary skill has a reasonable expectation of success in substituting the enzyme of Marklund with that of Trova because again such composition preparation methods are well established in the prior art.

Claims 1-7, 20-21 are rejected under 35 U.S.C. 103(a) as being under 35 U.S.C. 103(a) as being unpatentable over Choung et al. (Journal of Investigative-Dermatology, 122(3), pp A143, 2004, abstract) in view of current pharmaceutical and cosmetic composition preparation methods and in view of current skin diasese treatment methods.

It is noted that applicant claims foreign priority. However, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

In the absence of said translation, Choung renders instant invention obvious because it suggests methods of skin disease treatment and composition (both cosmetic and pharmaceutical) preparation utilizing EC SOD, prior to this invention.

Applicant can appreciate that once the role of said enzyme in skin damage is known current methods of skin disease treatments and current composition preparation utilizing said enzyme are totally within the expertise of prior art and are merely routine, rendering the invention obvious.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (571)

272-0932. The examiner can normally be reached on Tues.-Fri., from 7:00 a.m to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleene Kerr Bragdon can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

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